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EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,405	COSSARIZZA, ANDREA	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/30/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment of claims 1 and 2 and submission of new claims 17-24 in the paper filed on 02/23/2007 is acknowledged.

Claims 1-24 are pending and at issue.

Applicant's arguments filed on 02/23/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

For ease of reference, some of the maintained rejections are also noted in this section and discussed more fully in a later section.

I. Objections to Specification **Withdrawn**

2. The objection for lack of a section titled "Brief Description of the Drawings" is withdrawn in light of the Applicant's amendment of the specification to include such a titled section. The objection to the drawings is withdrawn in light of the Applicant's amendment to correctly identify the symbols in the drawings.

3. The objection for failure to properly identify trademarks TEXAS RED™ and BLACK HOLE QUENCHER2™ is withdrawn in light of Applicant's amendment to properly identify these trademarks.

II. Claim Objections (Item 4) **Withdrawn**

4. The objection to claim 1 for unclear grammar is withdrawn in light of Applicant's amendment of this claim.

III. Rejections under 35 USC § II2/second paragraph

First Rejection for Indefiniteness (Item 5a) **Withdrawn**

5. (a) Applicant's arguments, see Applicant's section III.A, filed on 02/23/2007, with respect to claims 1-16 have been fully considered and are persuasive. The rejection of claims 1-16 for the indefinite use of the term "CN" are withdrawn in light of Applicant's amendment of claims 1 and 2.

(b) Applicant presents no argument against the rejection of claims 1-16 for the how the ratio of the concentrations of NucSeqI' and NucSeqII' related to determining copy number, see Applicant's section III.B, filed on 02/23/2007. However, these rejections are withdrawn in light of Applicant's clarifying amendments of claim 1.

Third Rejection for Indefiniteness (Item 6) Maintained

6. The rejection of claims 1-16 for indefiniteness is maintained, please see below.

Fourth Rejection for Indefiniteness (Item 7) Maintained

7. The rejection of claims 1, 3-5, 8-9, and 11-15 for indefiniteness is maintained, please see below.

Fifth Rejection for Indefiniteness (Item 8) **Withdrawn**

8. The rejection of claims 2, 6, 7, 9, 10, 13, 14, and 16 for insufficient antecedent basis of the recitation of "cell" are withdrawn in light of Applicant's submission of new claim 17 and amendment to the claims.

Sixth Rejection for Indefiniteness (Item 9) Maintained

9. The rejection of claims 7-9 for indefiniteness is maintained, please see below.

Seventh Rejection for Indefiniteness (Item 10) Maintained

10. The rejection of claims 10-16 for indefiniteness is maintained, please see below.

IV. Rejections under 35 USC § II2/ first paragraph (Items 11-13) **Withdrawn / New Grounds**

11. Applicant's arguments, see Applicant's section IV, filed on 02/23/2007, with respect to the rejection(s) of claim(s) 1-16 under 35 USC § II2/ first paragraph have been fully considered and are persuasive.

12. Therefore, the rejection has been withdrawn.

13. However in view of claim amendments, new grounds of rejection are made as to the scope of the invention which is enabled, please see below.

V. PRIOR ART REJECTIONS

A. Rejections under 35 USC § 102(b) - **Withdrawn** (Item 14)

14. Applicant's arguments, see Applicant's Section V.A., filed on 02/23/2007, with respect to claims 1-3 and 6 have been fully considered and are persuasive. The rejection of claims1-3 and 6 under 35 U.S.C. 102(b) as being anticipated by Ginzinger et al. (2002) has been withdrawn.

B. Rejections Under 35 USC § 103(a) - **Withdrawn** (Item 15)

15. Applicant's arguments, see Applicant's Section V.B., filed on 02/23/2007, with respect to claims 1-3 and 6 have been fully considered and are persuasive. The rejection of claims 1-3 and 6 under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (1997) has been withdrawn.

Rejections that are Maintained and New

Specification

16. Examiner acknowledges Applicant's correction of the registered trademark ICYLER® to include the registered symbol. However this registered trademark should be capitalized as well.

The use of the trademark ICYLER® has been noted in this application. It and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

III. Rejections under 35 USC § II2/second paragraph

Fourth Rejection for Indefiniteness (Item 7)

17. The rejection of claims 1, 3-5, 8-9, and 11-16 for indefiniteness is maintained. Applicant's arguments filed on 02/23/2007 have been fully considered but they are not persuasive. Although amended, claim 1 still does not recite a step "of determining the copy number of a first nucleotide sequence". Thus this rejection is maintained.

Sixth Rejection for Indefiniteness (Item 9) Maintained

18. Applicant's arguments, see Applicant's section III.F, filed on 02/23/2007, with respect to claims 7-9 have been fully considered and are not persuasive. The rejection of claims 7-9 is maintained.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "NucSeqI' " in claim 1 is used by the claim to mean "corresponding to NucSeqI ", while the accepted meaning is "complementary to NucSeqI ". The

uncommon definition is not clearly defined in the specification. In argument, Applicant states that "a careful review" at page 35 to page 4 line 5 will reveal the uncommon definition. In argument, Applicant also states that: "It **should be** evident that the sequences of NucSeqI and NucSeqI' must have a relatively high degree of homology . . . " (emphasis by Examiner). However, since the definition is uncommon and integral to the claimed invention, the definition must set forth this relatively high degree of homology by clearly redefining the term in this manner.

Seventh Rejection for Indefiniteness (Item 10) Maintained

19. Applicant's arguments, see Applicant's section III.G, filed on 02/23/2007, with respect to claims 10-16 have been fully considered and are not persuasive. The rejection of claims 10-16 is maintained.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "NucSeqII' " in claim 1 is used by the claim to mean "corresponding to NucSeqII ", while the accepted meaning is "complementary to NucSeqII ". The uncommon definition is not clearly defined in the specification. In argument, Applicant states that "a careful review" at page 35 to page 4 line 5 will reveal the uncommon definition. In argument, Applicant also states by example that: "It

should be evident that the sequences of NucSeqI and NucSeqI' must have a relatively high degree of homology . . . " (emphasis by Examiner). However, since the definition is uncommon and integral to the claimed invention, the definition must set forth this relatively high degree of homology by clearly redefining the term in this manner.

New Rejections for Indefiniteness

20. New claims 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining the copy number of a first nucleotide sequence as recited in the preamble of claim 1.

21. New claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining the copy number of a first nucleotide sequence as recited in the preamble of claim 24.

22. New claims 17-23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed.

Cir. 1999). The terms "NucSeqI' " and "NucSeqII' " in claims 1 and 24 are used by the claims to mean "corresponding to NucSeqI "and "corresponding to NucSeqII " respectively, while the accepted meaning is "complementary to NucSeqI "and "complementary to NucSeqII " respectively. The uncommon definitions are not clearly defined in the specification.

New Claim Rejections - 35 USC § 112 Second Paragraph

23. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "monitored by flourescence" in line 23. There is insufficient antecedent basis for this limitation in the claim. Lack of antecedent basis for " monitored by flourescence" renders the monitoring of the amplification indefinite. Subsequent dependent claims 3-5, 8, 11, 12, and 17-23 are also rendered indefinite.

Claim 24 recites the limitation " monitored by flourescence" in line 22. There is insufficient antecedent basis for this limitation in the claim. Lack of antecedent basis for "monitored by flourescence" renders the monitoring of the amplification indefinite. Subsequent dependent claims 2, 6, 7, 9, 10, and 13-16 are also rendered indefinite.

It is unclear from where the fluorescence in the claims originates. While any of nucleotides, primers, polymerases, and probes as recited claims 1 and 24 can be fluorescently labeled; there is no recitation of which, if any, of these is fluorescently

labeled. If the fluorescence is endogenous, it is unclear what component(s) is(are) fluorescing.

24. Claim 2 recites the limitation "the absolute CN of NucSeqII" in line 5. There is insufficient antecedent basis for this limitation in the claim. Lack of antecedent basis for " the absolute CN of NucSeqII " renders the monitoring of the amplification indefinite. Subsequent dependent claims 6, 7, 9, 10, and 13-16 are also rendered indefinite. It is unclear where one would obtain "the absolute CN of NucSeqII " in order to use the claimed invention.

25. Claims 1, 3-5, 8, 11, 12, and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the CN of NucSeqI and the CN of NucSeqII each relate to the relative CN as given in the formula in step 1(3) of claim 1. It is unclear as to what the relationship is of CN of NucSeqI to Conc-I_{SCI} and what the relationship is of CN of NucSeqII to Conc-II_{SCII}. Neither Conc-I_{SCI} nor Conc-II_{SCII}, as recited, need be related to the CN of NucSeqI and the CN of NucSeqII, respectively. When "Conc" is a concentration of weight per volume, there is no apparent relationship to copy number. For this standard definition of concentration, it is unclear how a ratio of weight per volume concentrations of Conc-I_{SCI} to Conc-II_{SCII} in the formula of claim 1 can yield a relative CN, a relative Copy Number. Copy Number, it is noted, is an expression of a number of things, the number of copies of a sequence here, and is not an expression of

the weight of things. If "Conc" were limited to molarity which is a measure of the number of things (moles of molecules where the molecule can be a sequence) per volume, then the formula can yield a relative copy number; however no such limitation is found in the claims. Examiner also could find no definition in the specification limiting "Conc" to a measure of the number of things per volume.

26. Claims 24, 2, 6, 7, 9, 10, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how Conc-I_{SCI} and Conc-II_{SCII} each relate to the relative CN as given in the formula in step 1(3) of claim 24. It is further unclear as to what the relationship is of CN of NucSeqI to Conc-I_{SCI} and what the relationship is of CN of NucSeqII to Conc-II_{SCII}. It is further unclear as to what the relationship is of CN of NucSeqI to Conc-I_{SCI} and what the relationship is of CN of NucSeqII to Conc-II_{SCII}. It is noted that "Conc" is not limited and thus can be concentration of weight per volume. And thus it is further unclear how a ratio of weight per volume concentrations of NucSeqI and NucSeqII (Conc-I_{SCI} and Conc-II_{SCII} respectively) in the formula of claim 1 can yield a relative CN, a relative Copy Number. Copy Number, it is noted, is an expression of a number of things, the number of copies of a sequence here, and is not an expression of the weight of things. If "Conc" were limited to molarity which is a measure of the number of things (moles of molecules where the molecule can be a sequence) per volume, then the

formula can yield a relative copy number; however no such limitation is found in the claims.

New Claim Rejections - 35 USC § 112 First Paragraph

27. Amended and new claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection using probes with both quenchers and fluorophore, does not reasonably provide enablement for detection by a fluorophore alone by any measure of concentration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1-24 broadly recite any fluorescent method of monitoring without any limitation on what is fluorescing and any expression of concentration. However, the art teaches the use of molar concentration to determine copy numbers and relative copy numbers as taught by Ginzinger et al. (2000), Ginzinger et al. (2002), Zhang et al. (1997), and Zhang et al. (1997). Furthermore, in each of these teachings it is clear what

the fluorescent moiety is and how the assay format leads to a fluorescent measurement that is related to copy number. These references also go into detail on the amplification technique used how those techniques are suited to determining copy number.

Working Examples

The specification provides two working examples but only one method of determining copy number using: (1) a probe labeled with a quencher and fluorophore, (2) amplification by real time PCR, and (3) standard curves constructed using known copy numbers of controls per set volume, a very specific expression of concentration, even more specific than molar concentration.

Guidance in the Specification.

The specification provides no evidence that methods other than a probe with a quencher and fluorophore can be used successfully. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification does not discloses how labeling of any component other than a probe would work. The specification doe not disclose how general fluorescence would work, would a separation step be needed introducing problems with recovery.

The unpredictability of the art and the state of the prior art

The state of the art is such that determination of copy number is not a simple task. In determining copy number, Ginzinger (2002) states: "Successful application of real-time Q-PCR is not trivial" (see 3rd sentence of Abstract).

The post filing date art further confirms the unpredictability of this area. As noted by Bustin et al. (2005): "Worryingly, the extent of the unreliability of quantitative RT-PCR data [including copy number], and its effect on their biological validity, is still not widely appreciated or acknowledged" (see p. 597, 2nd column 2nd sentence). Bustin et al.

elaborates:" The principle of quantification is straightforward . . . .In practice, the relationship between target copy number and detection is not as clear-cut. First, reproducible quantification of any low abundance target (<1000 copies) is problematic due to the inherent limitation of PCR amplification of small amounts of template . . . Secondly, since many biological samples contain inhibitors of the RT and/or the PCR step . . . Thirdly, it is essential to apply a normalization strategy to control for the amount of starting material, variation of amplification efficiencies and differences between samples" (see p. 599, and the 1st paragraph in the section ***Normalisation***).

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to encompass the claims as written, including the labeling of any one or some combination of nucleotides, primers, probes, polymerases, and any other reagent used; the choice of fluorescent label(s); the exploration of endogenous fluorescence and distinguishing this from background flruoescence, the use of homogeneous or heterogensous format; the use of competitive or non-competitive format. Choice and optimization of these parameters and formats would require a very large quantity of experimentation. This would require considerable inventive effort, upon effective reduction to practice, not providing any guarantee of success.

Guidance in the Specification.

The specification provides no evidence that monitoring fluorescence of any component would be feasible to determine relative copy number. For one instance, the specification does not disclose how labeling a polymerase with a fluorphore can be used to determine relative copy number. The lack of guidance provided by the

specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

Level of Skill in the Art

To use the broadly claimed invention, the level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in an unpredictable art where several problems affect a successful measurement of relative copy number the factor of unpredictability weighs heavily in favor of undue experimentation. Further, the prior art and the specification provides insufficient guidance to demonstrate that the multitude of possible methods claimed would be successful. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of and but one working method and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the methods of the claims as broadly written.

Prior Art

28. No prior art was found which teaches or fairly suggests a nucleic acid amplification technique that uses two nucleic acid sequences on a single vector as controls to determine the relative copy number ratio of two corresponding nucleic acid sequences. The closest prior art found was Ginzinger et al. (2002) and Zhang et al. (1997) each of whom teach use of known nucleic acid sequences to determine relative

copy numbers of unknown nucleic acid sequences. However, neither Ginzinger et al. (2002) nor Zhang et al. (1997) teach or fairly suggest a control or standard which has two nucleic acid sequences on a single vector.

Conclusion

29. Claims 1-24 are rejected.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-

9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
April 27, 2007

MS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/30/07